IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA)
PHARMACEUTICAL COMPANY LTD.,)
TAKEDA PHARMACEUTICALS U.S.A.,)
INC., TAKEDA PHARMACEUTICALS)
INTERNATIONAL AG, and TAKEDA)
PHARMACEUTICALS AMERICA, INC.,) C.A. No. 18-088-LPS
) CONSOLIDATED
Plaintiffs,)
v.)
)
APOTEX INC., et al.,)
)
Defendants.)
)

MEMORDANUM ORDER

At Wilmington, this 8th day of January, 2021, the Court, having considered Defendants

Sandoz Inc. and Lek Pharmaceuticals d.d.'s Motion for Partial Judgment on the Pleadings under

Fed. R. Civ. P. 12(c) and to Dismiss for Lack of Subject Matter Jurisdiction under Fed. R. Civ. P.

12(b)(1), and the papers submitted in connection therewith (*see* D.I. 908-11, 937, 944; *see also*

985 at 7);

IT IS HEREBY ORDERED that the Motion (D.I. 908) is GRANTED.
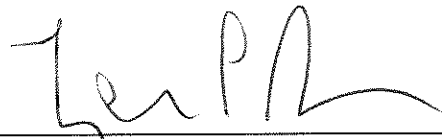
The substance of the motion is not disputed. Plaintiffs' request that Sandoz be required to

provide notice if it amends its ANDA to add a section viii statement is denied. As Sandoz states,

"Plaintiffs cite no statutory or other legal authority to support this unprecedented request." (D.I. 944 at

2; *see also generally Watson Labs., Inc. v. Sebelius*, 2012 U.S. Dist. LEXIS 185685, at *9 (D.D.C.

Oct. 22, 2012) ("Filing a section viii statement is not an act of infringement, so it does not require

applicants to provide notice to the pioneer applicant or wait thirty months for FDA approval.").

IT IS FURTHER ORDERED that:

1. Counts V-VI of the Third Amended Complaint for Patent Infringement Against

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Sandoz Inc. and Lek Pharmaceuticals d.d. (D.I. 809) are dismissed without prejudice.

2. Sandoz Inc.'s Ninth and Tenth Counterclaims set forth in Defendants Sandoz Inc. and

Lek Pharmaceuticals d.d.'s Answer and Affirmative Defenses and Sandoz's Inc.'s

Counterclaims to Third Amended Complaint for Patent Infringement (D.I. 845) are

dismissed without prejudice.

3. The parties shall bear their own attorneys' fees and costs.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

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